87 – 90. (Canceled).

REMARKS

Claims 85 and 86 are pending in the application.

- Claims 85 and 86 are objected to.
- Claims 85 and 86 are rejected under 35 USC 112, second paragraph (indefiniteness).
- Claims 85 and 86 are rejected under 35 USC 101.
- Claims 85 and 86 are rejected under 35 USC 112, second paragraph (enablement).

Claims Amendments

Claims 85 and 86 have been amended to make the terminology of steps b) and step d) uniform. Specifically, the phrase "an antibody generated to the central region of beta-amyloid SEQ ID NO.: 3" used in step b) has been used to replace the phrase "antibody specific for a beta-amyloid epitope" of step d).

Amendments have also been made consistent with the Examiner's remarks with regard to Claims Objections, as detailed directly below.

Further, Claim 86 has been amended in response to the Examiner's remarks directed towards indefiniteness, as detailed below.

Claims Objections

Claims 85 and 86 are objected to for the following formalities. The Examiner takes the brackets around "SEQ ID NO.: 3" as a typographical error and requests correction. The claims have been amended consistent with the Examiner's remarks.

Claims 85 and 86 are objected to because of the preamble is not related to the active steps of the invention. Corrections consistent with the Examiner's remarks have been made.

Rejection under USC 35, 112, second paragraph (Indefiniteness)

The Examiner has rejected Claim 85 as being indefinite in regard to the phrase "physiological levels of albumin."

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A)The content of the particular application disclosure;
(B)The teachings of the prior art; and

> (C)The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.
>
> MPEP, 2173.02

and,

> In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine **whether the claim apprises one of ordinary skill in the art of its scope** and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent.
>
> MPEP, 2173.02, **emphasis added**.

One of skill in the art understands that "physiological levels of albumin" constitute a physiological range, *i.e.*, a range found physiologically. Values in the physiological range may be within a "normal" range or, in rare cases such as a disease, the values may be higher or lower than the "normal" range. However, since these values are found physiologically they also, by definition, are within the scope of "physiological levels of albumin." As is stated in the pending Office Action, "the "physiological levels" of the claim encompass levels that lie outside what is considered in the art to be normal levels and includes the physiological levels associated with …" The most relevant point in this statement is that even physiological levels of albumin that are not "normal" are also considered to be "physiological levels." Thus, the phrase "physiological levels of albumin" is known to those of skill in the art and is, therefore, definite. In view of these remarks, the Applicant respectfully requests the withdrawal of the rejection.

The Examiner has rejected Claim 86 as being indefinite for using the term "about" with respect to the phrase "about 60 mg/ml of human serum albumin." Specifically, the Examiner states "one of ordinary skill in the art would not be reasonably apprised as to whether a method that taught every other limitation within the claim but taught detection in the presence of, for example, 55 mg/ml or 65 mg/ml of albumin would fall within the metes and bounds of the invention." Pending Action, page 4. The Applicant respectfully disagrees.

The Applicant submits that one of ordinary skill in the art would understand that the term "about" in the context of the presently claimed invention would refer to a very narrow range around the concentration of 60 mg/ml. However, and solely to advance the Applicant's business interest and without necessarily acquiescing to the Examiner's position, the Applicant has amended the claim to remove the word "about."

Rejection under 35 USC 101

Contrary to Examiner's assertion, the claims as pending have specific and substantial utility, as provided for in the specification as filed. The claims are directed towards, briefly, a method of forming and detecting an immune complex formed between beta-amyloid in the presence of physiological levels of serum albumin and an antibody generated to the central region of beta-amyloid SEQ ID NO.: 3.

In the abstract of the pending application it is stated: "The present invention also provides a method for sequestering free β-amyloid in the blood stream for an animal (*i.e.*, physiological levels of albumin) by intravenously administering antibodies specific for β-amyloid (*i.e.*, an antibody generated to the central region of beta-amyloid SEQ ID NO.: 3) to the animal in an amount sufficient to increase retention of β-amyloid in the circulation" (*i.e.*, form an immune complex). And, "Therapeutic applications of these methods include treating patients diagnosed with, or at risk for Alzheimer's disease." Abstract.

Further, as illustrated in paragraph [0088] and Table 7 of the pending specification, the anti-Aβ antibodies of the present invention are able to sequester beta-amyloid in the presence of physiological levels of serum albumin thereby forming an immune complex (Claims 85 and 86, steps a), b) and c)). The forming of an immune complex in physiological levels of serum albumin has specific and substantial utility for changing the "equilibrium distribution of Aβ in the body." Increased beta-amyloid levels in the brain have been correlated with the onset and progression of Alzheimer's disease. Since antibodies cannot cross the blood-brain barrier, this may be the only practical method for reducing beta-amyloid levels in the brain. See, paragraph [0088]. Thus, forming an immune complex in physiological levels of serum albumin has the demonstrated utility of reducing beta-amyloid levels in the brain. Contrary to the Examiner's assertion, this is not a vague or general utility. This is a specific and substantial utility of which the means of doing so are not found in the prior art. Detection of said immune complex (Claims 85 and 86, step d)) permits the clinician to monitor progression of the formation of the immune complex, treatment and/or disease. See, Table 7.

Further still,

> If reasonably correlated to the particular therapeutic or pharmacological utility, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process. MPEP, 2107.03, III.
>
> "…the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. MPEP, 2107.03, I.

> Most striking is the fact that in those cases where an applicant supplied a reasonable evidentiary showing supporting an asserted therapeutic utility, almost uniformly the 35 U.S.C. 101-based rejection was reversed. MPEP, 2107.03, III.

The Applicant submits that the disclosure, the *in vitro* data (see, Table 3) and the mouse model (see, Table 7) of the present specification are sufficient to meet this requirement.

The Examiner further states that the asserted "utilities within the specification pertain to unclaimed embodiments…" Pending Action, page 6. However, there is no requirement that the claim recite the utility, only that the claimed invention has utility. The Applicant submits for the reasons herein that the invention as claimed meets the legal requirements for utility under 35 U.S.C. 101.

In view of the forgoing remarks, the Applicant respectfully requests the withdrawal of the pending rejection and allowance of the claims.

Rejection under USC 35, 112, first paragraph (Enablement)

Claims 85 and 86 are rejected under 35 USC 112, second paragraph for alleged lack of enablement. The Applicant respectfully traverses this rejection.

First, the Examiner rejects the claims for failing to comply with the enablement requirement because "the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention." Pending Action, page 8. Applicant has addressed the Examiner's concerns regarding utility above. In view of the invention having a specific or substantial utility for the reasons given above, the Applicant respectfully requests the withdrawal of the pending rejection and allowance of the claims.

Second, the Examiner cites Sohn, *et al.*, for teaching "a circulating serum antibody against A-beta … has not [been] identified yet." Pending Action, page 9. Examiner also cites Gaskin for teaching the "inability to detect {A-β} antibodies in patients' sera." Pending Action, *Ibid*. However, the cited references are off point. The present invention does not have the element of detecting a free circulating Aβ antibody in patients' sera. Rather, the present invention is directed to detecting an immune complex comprising an antibody "generated to the central region of beta-amyloid SEQ ID NO.: 3" and an antigen. Thus, the cited references are not germane to the presently claimed invention.

In view of the forging remarks, the Applicant respectfully requests the withdrawal of the pending rejection and allowance of the claims.

Summary

In light of the above amendment and attendant remarks, consideration of the subject patent application is respectfully requested. If an interview would be beneficial to the prosecution of this case, Applicants respectfully request that Examiner MacFarlane contact the representatives of record. Any deficiency or overpayment should be charged or credited to Deposit Account No. 50-4514.

Respectfully submitted,

/Kevin M. Farrell/

Kevin M. Farrell
Attorney for Applicants
Registration No. 35,505
(603) 433-6300

Portsmouth, NH
Date: May 6, 2010